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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/832,424	04/11/2001	Carlo M. Croce	08321-0185 US1	9552

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Daniel A. Monaco
DRINKER BIDDLE & REATH LLP
One Logan Square, 18th and Cherry Streets
Philadelphia, PA 19103-6996

EXAMINER

WILSON, MICHAEL C

ART UNIT	PAPER NUMBER
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1632

DATE MAILED: 06/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary

Application No.

09/832,424

Applicant(s)

CROCE ET AL.

Examiner

Michael C. Wilson

Art Unit

1632

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 March 2004.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2,3,5-9,13,15,17,19 and 21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2,3,5-9,13,15,17,19 and 21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>3-3-04</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 2, 3, 5-9, 13, 15, 17, 19 and 21 remain pending and are under consideration in the instant office action.

Applicant's arguments filed 3-3-04 have been fully considered but they are not persuasive.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Objections

In claims 2 and 3, after the phrase "a termination codon in exon 5", the phrase "of the FHIT gene" should be added for clarity.

Claim Rejections - 35 USC - 112

Claims 2, 3, 5-9, 13, 15, 17, 19 and 21 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a transgenic mouse whose genome comprises a heterozygous disruption in the mouse FHIT gene, wherein said disruption causes increased induction of tumor formation, does not reasonably provide enablement for transgenic mice with a homozygous disruption in FHIT or for disrupting any FHIT gene in the mouse. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

Claims 2 and 3 require the a transgenic mouse having a disruption in an FHIT gene that displays increased susceptibility to visceral or sebaceous tumor formation or

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increased susceptibility to tumor formation upon being exposed to NMBA relative to FHIT +/+ mice. Claim 6 requires the disruption is homozygous.

The rejection regarding enablement for a mouse with a homozygous disruption of FHIT having the phenotype claimed (claim 6 or as broadly encompassed by claims 2 and 3) has been withdrawn in view of Zanesi (PNAS, Aug. 28, 2001, Vol. 98, No. 18, pg 10250-10255). It is noted that applicants' argument on pg 7, line 5, had an error. It is readily apparent that "heterozygous FHIT -/" was in error and should have been "homozygous FHIT -/" because the rejection is based on the lack of enablement for homozygous mice.

Claims 2 and 3 encompass disrupting any FHIT gene. The art only taught one FHIT gene in the mouse. The spec does not teach any other FHIT gene that could be disrupted in the mouse. It would require one of skill undue experimentation to determine other FHIT genes. If other FHIT genes exist, it would have been unpredictable whether such mice would have the phenotype claimed given the unpredictable state of the art regarding the phenotype of transgenic mice. Therefore, the specification does not enable disrupting any FHIT gene as broadly claimed.

Applicants argue the amendment addresses this aspect of the rejection.

Applicants' argument is not persuasive. The claims still encompass a disruption in any FHIT gene, while the specification is limited to a disruption in the mouse FHIT gene. Replacing the phrase "a FHIT gene disruption" with the phrase "a disruption in the mouse FHIT gene" would overcome this rejection.

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The rejections of claims 2-9, 13, 15, 17, 19 and 21 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention have been withdrawn in view of the amendment.

Claims 2, 3, 5-9, 13, 15, 17, 19 and 21 remain free of the prior art because the prior art did not teach or suggest transgenic mice having a disruption in an FHIT gene having increased susceptibility to visceral or sebaceous tumor formation or to tumor formation upon being exposed to NMBA.

Conclusion

The following prior art remains of record and not relied upon because it is considered pertinent to applicant's disclosure: Huebner et al. (Annu. Rev. Genet. 1998. Vol. 32, pg 7-31).

No claim is allowed.

Inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C. Wilson who can normally be reached on Monday through Friday from 9:00 am to 5:30 pm at 571-272-0738.

Questions of a general nature relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-1235.

If attempts to reach the examiner, patent analyst or Group receptionist are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached on 571-272-0804.

The official fax number for this Group is (703) 872-9306.

Michael C. Wilson



**MICHAEL WILSON
PRIMARY EXAMINER**